Multikine® is a Leukocyte-Interleukin Injection containing only trace quantities of IL-12 for all species. See specification at paragraphs 25 and 26 on page 11. Hence, the specification provides sufficient direction and guidance for making the claimed composition and satisfies the written description requirement under § 112, ¶ 1.

Regarding the various documents produced by the Examiner reciting the trademark Multikine® and thus raising the concern that the presently claimed product may have been made publicly available or patented prior to the claimed invention, Applicants respond by noting that the formulation for Multikine® has changed over time and that the current formulation as presently claimed has not been made publicly available or patented prior to the claimed invention. Moreover, the presently claimed product to which Multikine® refers is set forth in such clear language that the disclosure sufficiently identifies the claimed product. In support thereof, Applicant submits an affidavit under § 1.132 by the inventor Dr. Eyal Talor averring that the presently claimed formulation has not been made publicly available and/or previously patented.

Regarding the Assignee's website, the incorrectly recited term of "patented" before "Multikine®" has been deleted.

No new matter within the meaning of § 132 has been added by any of the amendments.

Accordingly, Applicant respectfully requests the Examiner to enter the indicated amendment canceling the withdrawn claims and to withdraw the outstanding rejection in view of the arguments and allow all presently pending claims.

1. Rejection of Claims 24-27 under 35 U.S.C. § 112, ¶ 1

The Office Action rejects claims 24-27 under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. The Office Action states:

> Newly amended claims 24 and 26 are now limited to cytokine mixtures "with the proviso that IL-12 is present in only trace quantities". However, the only support in the specification for a cytokine mixture that contains trace amounts of IL-12 is to the trademarked brand of cytokines termed Multikine® (page 12, line 30). The fact that one particular and distinct brand of packaged cytokines contains trace amounts of IL-12 does not provide sufficient direction and guidance to the features currently claimed. Hence, applicants appear to be claiming a subgenus of cytokine compositions not supported by the specification as originally filed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679,683 (CCPA 1972) and MPEP 2163.05. Hence, the instant claims now recite limitations, which were not

> clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of35 U.S.C. 112.

Applicant respectfully traverses the rejection because the specification provides support for a cytokine mixture that contains trace amounts of IL-12 for the trademarked brand of cytokines, Multikine®, for all species. See specification at paragraphs 25 and 26 on page 11. Contrary to the Office Action's assertion that the proviso for trace quantities of IL-12 is only related to one particular and distinct brand of packaged cytokines, Applicant notes that the proviso applies to all species of the composition. Therefore, the proviso for trace amounts of IL-12 extends to all subgenus of the presently claimed cytokine compositions.

Rule of Law

The first paragraph of 35 U.S.C. § 112 requires that the "specification shall contain a written description of the invention . . .". To satisfy the requirement, the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Vas-Cath, Inc. v. Mahurkar,

935 F.2d 1550, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991). A description as filed is presumed to be adequate, unless the examiner presents sufficient evidence or reasoning to rebut the presumption. See e.g., In re Marzocchi, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971).

The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description wherein the Examiner has the initial burden of proving why a person skilled in the art would not recognize a description of the invention defined by the claims. See In re Wertheim, 541 F.2d at 263-64, 191 U.S.P.Q. at 97; "Guidelines for the Examination of Patent Application Under the 35 U.S.C. 112, §1, "Written Description" Requirement" Federal Register, Vol. 66, No. 4, (Friday, January 5, 2001).

Presently pending independent claims 24 and 26

Independent claims 24 and 26 recite a serum-free and mitogen-free cytokine mixture, comprising:

specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ and GM-CSF to Interleukin-2 (IL-2) as follows:

IL-1β to IL-2 at a ratio range of 0.4 - 1.5;

TNF-α to IL-2 at a ratio range of 3.2 - 11.3;

IFN-γ to IL-2 at a ratio range of 1.5 - 10.9; and

GM-CSF to IL-2 at a ratio range of 2.2 - 4.8

with the proviso that IL-12 is present in only trace quantities.

The limitation that IL-12 is present in only trace quantities is clearly supported in paragraph 27 on page 12 of the specification. The paragraph reads "Multikine® contains only trace quantities (just above the level of detection of the assay) of IL-12".

Regarding the concerns over subgenus teachings, Applicant notes that such concerns are unwarranted given that the specification explicitly refers to the compositional make-up for all the various embodiments of "Multikine®" throughout the specification. See paragraphs 24 and 25. The teaching that Multikine® contains only trace quantities of IL-12 therefore applies to all subgenus of Multikine®. In other words, the teaching of IL-12 in trace quantities is a feature of all the various species of Multikine®.

Hence, the specification provides sufficient direction and guidance for making the claimed composition and satisfies the written description requirement under § 112, ¶ 1. Clearly, the specification as originally filed describes the subject matter in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

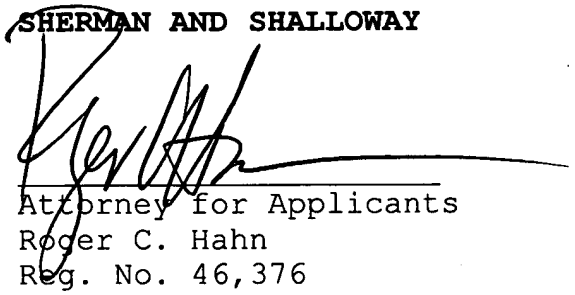
Accordingly, Applicant respectfully submits that claims 24-27 are fully supported by the specification and requests withdrawal of the § 112, ¶ 1 rejection.

CONCLUSION

In light of the foregoing, Applicant submits that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the pending claims and allow the pending claims. Favorable action with an early allowance of the claims pending is earnestly solicited.

Respectfully submitted,

SHERMAN AND SHALLOWAY



Attorney for Applicants
Roger C. Hahn
Reg. No. 46,376

SHERMAN AND SHALLOWAY
413 N. Washington Street
Alexandria, Virginia 22314
703-549-2282